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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/041,975	03/13/98	ALIZON M	2356.0011-06

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EXAMINER
PARKIN, J

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/12/98

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.	Applicant(s)
09/041,975	Alizon et al.
Examiner	**Group Art Unit**
Jeffrey S. Parkin, Ph.D.	1648

☒ Responsive to communication(s) filed on *13 Mar 1998*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-6 and 22* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-6 and 22* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Detailed Office Action

Status of the Claims

1. Acknowledgement is hereby made of the Amendment filed 13 March, 1998, wherein claims 7-21 were canceled without prejudice or disclaimer. Claims 1-6 and 22 are pending in the instant application.

35 U.S.C. § 119/120

2. If applicant desires priority under 35 U.S.C. § 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification following the title, preferably as a separate paragraph. The status of non-provisional application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No._____" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application. Applicants are advised that the status of several of the applications referred to under this section has changed (i.e., Serial No. '530 is abandoned; Serial No. '397 is U.S. Patent No. 5,773,602). Appropriate correction is required.

3. It is noted that applicants claim the benefit of priority under 35 U.S.C. § 119(a)-(d) based upon priority papers filed in an earlier application. In making such a claim, applicants should clearly identify the application containing said priority papers.

Drawings

4. The drawings filed in this application are objected to by the

Draftsperson under 37 C.F.R. §§ 1.84 or 1.152 as indicated. These drawings are acceptable for examination purposes only. Formal drawings with the appropriate corrections will be required when the application is allowed.

35 U.S.C. § 112, Second Paragraph

5. Claims 1-3 and 5-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Two separate requirements are set forth under this statute: (1) the claims must set forth the subject matter that applicants regard as their invention; and (2) the claims must particularly point out and distinctly define the metes and bounds of the subject matter that will be protected by the patent grant.

Claim 1, which refers to a virus comprising RNA corresponding to a cDNA of the recited figures is confusing. It is not readily manifest if applicants are referring to an actual viral preparation (i.e., LAV_{MAL} virions) or proviral molecular clones encoding the virus. Furthermore, since corresponding is defined in Webster's dictionary as being analogous, similar, or closely related to, it is not readily manifest if the claim language encompasses "genetically-related" viruses. Absent further clarification, the metes and bounds of the patent protection desired cannot be ascertained. If applicants intend to claim LAV_{MAL} virions, the following claim language is suggested: A composition comprising replication-competent, infectious lympadenopathy-associated virus (LAV) strain MAL, wherein said virus is prepared from a molecular clone having the nucleotide sequence set forth in Figures 7A-7I. Alternatively, if applicants intend to claim proviral clones, the following language is suggested: A recombinant, proviral, lympadenopathy-associated virus (LAV) strain MAL molecular clone having the nucleotide sequence set forth in Figures 7A-7I; or A phage clone, containing the

lympadenopathy-associated virus (LAV) strain MAL genome, having the C.N.C.M. biological deposit number I-551). Appropriate correction is required.

Claim 2 is confusing in simply reciting the cDNA of Figures 7A-7I. It is not readily manifest what subject matter is encompassed by the claims. For instance, do applicants intend to claim an isolated nucleic acid sequence having the LAV_{MAL} nucleotide sequence set forth in Figures 7A-7I? Or do applicants intend to claim a vector or plasmid comprising the LAV_{MAL} nucleotide sequence set forth in Figures 7A-7I? Absent further clarification the metes and bounds of the patent protection desired cannot be ascertained.

Claim 3 references a DNA recombinant which is vague and confusing. It is not readily manifest if applicants are referring to a plasmid or expression vector containing the cDNA of Figures 7A-7I. Absent further clarification the metes and bounds of the patent protection desired cannot be ascertained. Appropriate correction is required.

Claims 5 and 6 are incomplete for omitting essential positive methods steps, such omission amounting to a gap between the steps (refer to M.P.E.P. § 2173.05(q)). *Ex parte Erlich*, 3 U.S.P.Q.2d 1011 (Bd. Pat. App. & Inter. 1986). These claims fail to describe those salient steps that are required to practice the method. The claimed invention fails to recite sample and probe preparative steps, hybridization reaction conditions, detection steps, etc.). Applicants should clearly disclose those steps necessary for performing the claimed diagnostic method as supported by the disclosure.

35 U.S.C. § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 4 is rejected under 35 U.S.C. § 102(b) as being anticipated by Alizon *et al.* (1984). Alizon *et al.* (1984) disclose the preparation of lympadenopathy-associated virus (LAV) cDNA probes (refer to Figure 1 and first paragraph, page 758). Three cDNA clones were generated designated pLAV13, 75, and 82. These probes were capable of hybridizing to LAV (refer to Figure 2, page 758). Thus, this teaching appears to meet all the limitations of the claimed invention (i.e., a probe containing a nucleic acid sequence capable of hybridizing with LAV_{MAL}).

8. Claim 4 is rejected under 35 U.S.C. § 102(b) as being anticipated by Wain-Hobson *et al.* (1985). Wain-Hobson *et al.* (1985) disclose the preparation of lympadenopathy-associated virus (LAV) cDNA probes (refer to Results, "DNA Sequence and Organization of the LAV Genome," page 9 and Experimental Procedures, page 15). These probes are all capable of hybridizing to LAV-derived nucleic acids and meet all the limitations of the claimed invention.

35 U.S.C. § 103(a)

9. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

11. Claims 5 and 6 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Alizon *et al.* (1984) and Wain-Hobson *et al.* (1985) in view of Stabinsky (1988) and Saiki *et al.* (1987). As disclosed *supra* in the preceding paragraphs, Alizon *et al.* (1984) and Wain-Hobson *et al.* (1985) disclose the preparation of lympadenopathy-associated virus (LAV) cDNA probes (refer to Figure 1 and first paragraph, page 758 and Results, "DNA Sequence and Organization of the LAV Genome," page 9 and Experimental Procedures, page 15, respectively). Wain-Hobson *et al.* (1985) also provides the complete nucleotide sequence of LAV. These probes were useful in hybridization assays for the detection of LAV nucleic acids. These teachings do not disclose detection methods involving host tissues *per se*. However, both Stabinsky *et al.* (1988) and Saiki *et al.* (1987) provide diagnostic methods and kits employing oligonucleotide probes that are useful for detecting the desired target in host tissues. Thus, it would have been *prima facie* obvious to one having

ordinary skill in the art at the time the invention was made to employ the LAV-specific probes disclosed by Alizon *et al.* (1984) and Wain-Hobson *et al.* (1985) in host tissue detection assays, as taught by Stabinsky (1988) and Saiki *et al.* (1987), since this would facilitate the direct detection of LAV in patient samples.

Correspondence

12. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648.**

13. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be submitted directly to the Examiner through the following fax number: (703) 305-7939. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.

14. Any inquiry concerning this communication should be directed to **Jeffrey S. Parkin, Ph.D.**, whose telephone number is **(703) 308-2227.** The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, **Donald E. Adams, Ph.D.**, can be reached at **(703) 308-0570.** Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

JEFFREY STUCKER
PRIMARY EXAMINER

02 June, 1998